THE MINISTER OF HEALTH AND FAMILY WELFARE (DR. ANBUMANI RAMDOSS) : Sir, I beg to move:

That the Bill further to amend the Drugs and Cosmetics Act, 1940, be taken into consideration.

Sir, the Government had set up an Expert Committee under the Chairmanship of Dr. Mashelkar in February, 2003, to recommend measures for strengthening the drug regulatory system in the country as well as tackling the problems of spurious drugs. Based on the recommendations of Dr. Mashelkar Committee, a Bill was introduced in Rajya Sabha to amend the Drugs and Cosmetics Act, 1940, in order to make the penal provisions more stringent to tackle the problems of adulterated and spurious drugs. The Bill was referred to the Parliamentary Standing Committee for detailed examination. On receiving the recommendations of the Parliamentary Standing Committee, the same were examined extensively in the Ministry of Health and Family Welfare in consultation with the Ministry of Law and Justice. Most of the recommendations made by the Parliamentary Standing Committee have been accepted and are being incorporated in the Bill by way of official amendments. Apart from this, a few new provisions, to meet the requirements of current times, are also being incorporated in the Drugs and Cosmetics Act by way of official amendments. I, therefore, request that The Drugs and Cosmetics (Amendment) Bill, 2005 may be taken into consideration.

The question was proposed

श्री उपसभापति: डा0 सी0पी0 ठाकुर।

डा0 सी0पी0 ठाकुर (बिहार): उपसभापति महोदय, मैं आपके प्रति आभार प्रकट करता हूँ जो आपने मुझे इस विषय पर बोलने के लिए समय दिया।

यह बहुत ही महत्वपूर्ण बिल है। देश में स्पूरियस ड्रग्स के चलते बहुत तरह की घटनाएँ होती हैं, यह रोज अखबारों में निकलता है। इसलिए तत्कालीन सरकार, जिसमें हम लोग मंत्री थे और हमारे बाद जो स्वास्थ्य मंत्री थीं, श्रीमती सुषमा स्वराज जी, उन्होंने इस बिल को उस वक्त टेबल किया था। उसके बाद माशेलकर कमेटी अप्वायंट हुई और उन्होंने एक रिपोर्ट भी दी, लेकिन वह बिल फाइनली नहीं हो सका। सरकार ने रिजाइन कर दिया, इसके चलते वह लैप्स कर गया। अब हमारे माननीय मंत्री जी ने इसको लाया है, लेकिन उस वक्त जो सोचा गया था, इसको उससे थोड़ा नहीं बल्कि बहुत डायल्यूट कर दिया गया है। उस बिल में यह प्रोविजन था कि अगर कोई यह करता है, तो उसके लिए उसमें मृत्युदंड तक का प्रोविजन था। चूँकि दवा में मिलावट के कारण जो आदमी मर जाता है, उसमें एक तो यह है कि आप अच्छा होने के लिए जाते हैं और आप ऐसी दवा खरीद लेते हैं जिससे कि आप मर जाते हैं। इससे एक तरह से इंटेशनल पब्लिक की किलिंग होने लगती है। उसको रोकने के लिए मृत्युदंड के जैसा कुछ ऐसा कड़ा प्रावधान होना चाहिए जिससे आदमी डरे और इस तरह का काम नहीं करे। इस समय जितना ऐसे केसेज़ का जिक्र अभी अखबारों में जो होता रहता है, उससे कहीं ज्यादा स्पूरियस ड्रग्स की सेल इस देश में हो रही है। उसको कैसे पकड़ा जाएगा,

उसका प्रोविजन और उसकी जो सुविधा होनी चाहिए, वह स्टेट्स में नहीं है। इस तरह इसमें एक बात तो यह है कि इस बिल को थोड़ा और कड़ा करना चाहिए। जो पहले सोचा गया था, माननीय मंत्री जी उस पर सोचेंगे कि वे इसको कैसे और कड़ा करें। उसमें मृत्युदंड का जो प्रावधान था, वह उस हिसाब से ठीक ही रखा गया था।

इस देश में कैसे-कैसे स्पूरियस ड्रग्स बनते हैं, इसमें एक तो यह है कि एक कम्पनी ने कुछ ड्रग्स बनाए और दूसरी कम्पनी वाला, जिसके पास पैसा है, वह अच्छी मशीन खरीद लेगा और बिना लाइसेंस के उस तरह से एग्जैक्टली उसी तरह की नकल कर देगा। वह किसी को, बाहरी आदमी को, जल्दी पता नहीं चलता है कि वह स्पूरियस ड्रग है। लेकिन, जो ओरिजनल कम्पनी वाला है उसकी सेल उस इलाके में घट गयी, तो वह देखता है कि उसी तरह का एक ड्रग आ गया, कुछ थोड़ा-बहुत कहीं फर्क हो गया तब जाकर इस बात का पता चलता है। सबसे डिफिकल्ट स्पूरियस ड्रग में इसी तरह का ड्रग है। दूसरे तरह की स्पूरियस ड्रग वह होती है, जिसमें जितना अमाउंट दिया हुआ है, उसमें डोज़ लिखनी पड़ती है कि इतना रहेगा- 250 मि0ग्रा0, तो उसको 250 मि0ग्रा0 के बदले 200 मि0ग्रा0 दे दिया और 50 मि0ग्रा0 कम कर दिया। होम्योपैथी का अलग प्रिंसिपल है, लेकिन एलोपैथी में अगर आप ड्रग की डोज़ कम देते हैं तो वह उतनी असरदार नहीं होती है। यह दूसरे तरह का स्पूरियस ड्रग है। तीसरे तरह की स्पूरियस ड्रग वह है, जिसमें ड्रग रहती ही नहीं है। उसमें ड्रग के बदले आटा भर दिया या कुछ और भर दिया या दूसरे तरह की चीज़ भर दिया या कोई सस्ती चीज़ भर दिया। इस प्रकार तीन तरह की स्पूरियस ड्रग्स हैं।

इसमें एक डिफिकल्टी और है। इसका कानून सेंट्रल गवर्नमेंट बनाती है, लेकिन इसकी सब प्रकार की जाँच करना स्टेट गवर्नमेंट के हाथ में है। स्टेट गवर्नमेंट के पास उतना साधन नहीं है कि वह इसको कर सके। इस प्रकार इसमें और काम करने की आवश्यकता है। माननीय मंत्री जी इस पर विचार करेंगे कि एक तो स्टेट गवर्नमेंट को भी इतना स्ट्रेंथेन किया जाए कि अगर कहीं से भी स्पूरियस ड्रग की रिपोर्ट हो तो तुरंत उसकी जाँच हो जाए और पता चल जाए कि वह स्पूरियस है या नहीं, इसकी व्यवस्था होनी चाहिए। उसके लिए ड्रग्स इंस्पेक्टर की बहाली, उसके लिए मशीन देना, आदि हम समझते हैं कि स्टेट गवर्नमेंट के बूते नहीं हो सकता है। उसके लिए सेंट्रल गवर्नमेंट को मदद करनी पड़ेगी तब वह एक स्टेंडर्ड पर आएगा।

दूसरा यह जो ड्रग कंट्रोल का डिपार्टमेंट है, यह poorly equipped है। इसमें बहुत कम आदमी हैं। इस में रिटायर्ड आदमी जो गया, उसकी बहाली ही नहीं हो रही है। हम लोगों की जब सरकार थी तो ऐसा सोचा गया था कि अमेरिका में एफ0डी0ए0 के तहत जो डिपार्टमेंट है, वह बहुत ही साइंटिफिक डिपार्टमेंट है और अब हमारा देश भी आर्थिक रूप से तरक्की कर रहा है तो हमारे ड्रग कंट्रोल डिपार्टमेंट को भी हमें उसी लेवल का बनाना चाहिए क्योंकि अब इंडिया में भी ड्रग का सेल कम नहीं है। इंडियन कंपनीज भी सब तरह का ड्रग्स बना रही हैं और दुनिया के देशों में बेच रही हैं। वे बढ़िया ड्रग्स बनाती हैं, लेकिन यहां उस तरह का कंट्रोल नहीं है। फिर एफ0डी0ए0 यह भी करता रहता है कि यह ड्रग कम इफैक्टिव हो रही है तो *suo moto* वह चाहेगा तो उस ड्रग को डिसअलाउ कर देगा, डिसकंटीन्यु कर देगा, नोटिस देगा, मार्केट से विद्ड्रा कर लेगा। वह एक तरह से हर जगह फार्मेको विजिलेंस रखता है और उस पर काम करता है। इसलिए इसमें वह करने की आवश्यकता है और उसके लिए उसी तरह से मॉडीफिकेशन होना चाहिए। इस तरह यह बहुत ही महत्वपूर्ण बिल है। खासकर यह पब्लिक सेफ्टी का बिल है, इसलिए इस बारे में ज्यादा जोर देने की आवश्यकता है। मैं तो यही request करूंगा कि इस में जो प्रावधान डेथ पैनल्टी का किया गया था, उस की मंत्रीजी बहाली करें। इससे आदमी डरेगा, नहीं तो कोई डरता नहीं है। उसको एक साल की जेल हुई, उसके बाद फिर धड़ल्ले

से नकली दवा बनाना शुरू कर देता है। इसलिए उसको कड़ा बनाने की आवश्यकता है और जब कानून कड़ा होगा तो आदमी डरेगा।

हम कभी-कभी देखते हैं कि एक बच्चा जब बहुत बीमार हो जाता है तो उसके मां-बाप घबरा जाते हैं। फिर वह जो दवा लाते हैं, उस दवा के चलते बच्चा मर गया क्योंकि उस बीमारी की जो दवा उसे मिलनी चाहिए थी, वह नहीं मिली। इसलिए भी मैं समझता हूंकि इस कानून को रिवाइज करने और कड़ा बनाने की आवश्यकता है। इसके लिए जो भी जरूरी हो सभी तरीके लागू होने चाहिए। इसके साथ ही सेंट्रल गवर्नमेंट को एक बड़ी सरकार होने के नाते इस पर ज्यादा ध्यान देने की आवश्यकता है तभी अच्छे स्तर की दवाइयां बनेंगी। फिर कहीं भी टेस्ट हो तो खराब नहीं पाई जाएंगी। इसलिए इन सारी बातों पर ध्यान देने की आवश्यकता है। धन्यवाद।

SHRI SHANTARAM LAXMAN NAIK (Goa): Sir, I stand here to support this Drugs and Cosmetics (Amendment) Bill, 2005. It has taken some years for the Bill to see the light of the day. Nevertheless, it is an important Bill and in a lighter vein, I would request and suggest hon. Minister not to be after Shah Rukh Khan much, but be after the implementation of this serious Bill. ...*(Interruptions)*...

Sir, if we see the scenario of spurious drugs, it is very alarming. Although our pharmaceutical industry has got a turnover of about Rs.20,000 crores, export is about Rs.10,000 crores which is growing at the rate of 10 per cent for the last one decade. Thirty-five per cent of the world's spurious drugs are produced in India according to the WHO Report. Subsequently, I think, they have denied it. But, this is the alarming proportion of spurious drugs. We lose something like Rs.4,000 crores by way of taxes, etc. It is a loss to the exchequer. Turnover of spurious drugs is around 18 per cent. So, Sir, we can very well imagine the proportion under which this menace is going on. Those who are killed or those who get injuries on account of the use of these spurious drugs, those culprits are no less than terrorists because these people give slow death. In terrorism, it is instant death. That is the only difference. But hundreds of people, thousands of people die on account of these spurious drugs. There were various methods. Recycling is one method whereby powder injections are easily targeted. You can fill powder in them which are available freely everywhere. Then iodex, gripe water, these can be recycled easily. But the thing is that no proper rates are put, no investigation is done and no prosecution is filed. Some experts say that in Delhi, if you have a round in Bhagirathi Palace, you will know what the scenario is. This is before your eyes, and if you don't look what is happening around you, then absolutely, Sir, the blame will come on you. You are an efficient Minister. You have proved so. Now, in this sector, you must show some action so that many lives are saved. Again, refilling and relabeling is one way of marketing spurious drugs. Cheaper companies' drugs are put in the bottles etc., labels of standard companies are put and marketed. Now, in this case, sometimes it is very difficult to recognise a spurious drug from a standard drug. It is a wrong notion that just because earlier the punishment was not that high, there

4.00 P.M.

was no deterrent. The question is, as the law stands today, have we been able to prosecute people? Have we been able to investigate into the cases? How many people have been punished under the present provisions of law? That is the question. There is no guarantee that just because we enhance the punishment, the things will improve. Things will improve even with provisions of lesser punishment provided there is a proper investigation. Now, the question is, whether the death penalty should be there or not, is a debatable question. In some countries like Vietnam, United Arab Emirates, Oman, Bahrain, Kuwait and Qatar, I learn that there is a punishment for death. I will still say that it is a debatable issue. But nevertheless, if we know that by way of spurious drugs, death of hundreds of people can be caused, and if we say that that man should not be sent to the gallows, is something wrong. So, the question is, if somebody is causing death by this method, then we have to rethink whether there should be a death punishment or not. Perhaps, death can be a deterrent. I am not very sure whether it is a deterrent or not. But that can be one way of doing it, and I think, in extreme cases, death penalty must be provided for. Otherwise, that cannot be an effective deterrent.

Sir, as far as spurious drugs are concerned, we are also scared. We are covered by the CGHS. What is happening in the CGHS? Is there a way out? Are you checking it properly? What is the guarantee that our lives are safe when we take drugs from the CGHS dispensary? The CGHS all these years have been involved in various types of scandals, may be of spurious drugs. I think we must be very vigilant as far as CGHS is concerned. There was a talk of abolition of the CGHS. I do not know what the matter was. If it happens, even those drugs which we are getting right now, we will not be able to get them. The question is not of abolition of this scheme. The question is of improving, having standardization and making those who are at the helm of affairs responsible for the action. That is what you have to do as far as the CGHS is concerned.

Secondly, the counterfeiting of drugs by way of imitation has become very easy these days because of new technology. Even Government laboratories, I learn, cannot distinguish between a product which has been imitated and a product which is a genuine one. Imitation is so perfect that it is very difficult to make a distinction. We do not have that sort of laboratories to detect imitated drugs or imitated products also. Our Food and Drugs Administrative Machinery which is functioning there is not that much perfect or that much strong to handle this type of situations. You should have some sort of a mechanism, modern mechanism, which can detect these types of imitation. If we cannot detect imitated products, that will make the situation a more dangerous one.

Then, Sir, you think of appointing Special Courts in this matter. Ultimately, whenever we talk of appointing Special Courts under any legislation, what we, normally, do is, the judge who is functioning there, is designated as a Special Judge under this Act; nothing else. स्पेशल जज की

मीनिंग ही नहीं होती। The same thing you are doing. Either we should entrust the matter to the Sessions Court in a normal manner or should really designate Special Courts which alone could be assigned this work. They will only be dealing with those cases. If that is not possible, you give it to the normal Session Courts. Otherwise, don't call them 'Special Courts'. What is the sense in calling them 'Special Courts' if they are not entrusted with the task of handling these cases? This is not the case in your Ministry. In many other legislations, there is a provision for that. Therefore, Special Courts must have certain specific duties to be performed under that legislation. It is good that it has got this provision which has made these offences cognisable or non-bailable. Again, the question of added responsibility arises. Suppose you give this handle in the hands of the police machinery. Unless there is transparency, unless the anti-corruption machinery is strong enough to detect the actions of the police, that will be of no use. Therefore, whenever we entrust such powers to the police machinery, it should be seen that cases are filed; underhand money is not taken from the culprits, and that they are not let free. Who will look into that aspect, Sir? You have to co-ordinate with the Ministry of Home Affairs for that purpose. You may say that this is not your job; the police have to do that job. But some wing of your Ministry can look into this aspect. Unless that is done, corruption will be rampant even after these provisions come into force because there is additional scope for the police machinery to have their way. You also know that the drug lobby is very strong; they can handle these police people the way they want. And they will play with our lives. Therefore, here also, you have got additional responsibility.

Thirdly, Sir, we are, as I said earlier, responsible persons in our country, but if we see the WHO Report—whether it is a true report or not, is not known— it shows that 35 per cent of the spurious drugs the world over are produced in our country. But, Sir, a day will come when we will be in the wish list of several countries for the purpose of spurious drugs. But if some important countries which import drugs from us, start banning our drugs, if they start banning our pharmaceutical drugs, the industrial growth will slow down. Therefore, Sir, from that point of view also, you have to see that these spurious drugs' menace is reduced to the minimum.

Lastly, Sir, I would say that some sort of education has to be given to the people. I do not know how the position can be explained to them; it is very difficult also. But, Sir, people are to be educated for recognising the difference between spurious drugs and genuine drugs. Whether this is possible or not, I am not very sure because the perfection exists in this industry today. But you should have some sort of mechanism to see that the minimum education is given to the people about recognising the spurious drugs, staying away from their use and protecting themselves. Thank you very much.

SHRIMATI BRINDA KARAT (West Bengal): Sir, I am glad that these amendments are being brought because the adulterated drugs take human lives and gravely affect the health of those who take those drugs to get better. This is certainly an issue of great concern to this country, going by some of the statistics which have been given by the World Health Organisation. Whether we have to believe them, I don't know. I am sure, the hon. Minister will clarify that.

DR. ANBUMANI RAMDOSS: Sir, I just want to counter the point made by my friend and Mrs. Brinda Karat. They said that the World Health Organisation had said that 35 per cent of the Indian drugs was spurious. It is completely untrue. It is not true at all. They have denied it and I kindly request the hon. Members here not to say that 35 per cent of the drugs are spurious because the entire country is watching this today. Therefore, I would request the hon. Members not to say like that.

SHRIMATI BRINDA KARAT: There is no question of causing any panic or anything about this. But the issue is: Is there a problem of adulterated drugs in this country or not? That is the issue here. I think, there are three issues which we need to deal with. The first is: Who is responsible for adulterated drugs? Now, if you just look at the record of the big pharma companies that we have, what we are finding is that even the most sophisticated companies which are exporting drugs from this country are also outsourcing drug manufacturing. We find that in a large number of States there are very small scale units which are producing drugs, which are then sold as a particular brand of drugs. What is the Government doing about this? The reason why I am asking this is not that I am against the small scale manufacturing of drugs. If they have standards, if they are doing it, there is no harm in it. But the issue here is: Whose liability is it? Who gets prosecuted? No doubt, it should be the big pharma companies which are outsourcing that drug manufacture are responsible for this. But very often it is the small people who are caught and punished. I can give you an example. In this House, last year, in 2007, a question was raised as to the veracity of the report that a large number of raids were conducted in certain towns of Uttar Pradesh. They said that the raids were conducted. But who was responsible? Who was arrested? Was it the big pharma companies which found it out? No, I don't think so. Therefore, this is one issue, I think, which the Minister should address and which should also be addressed in law.

The second very important issue here is that when we use the term "spurious drugs" it is a very wide ranging term and there is also overlapping in different laws in this country. For example, one aspect of spurious drugs is that a particular company is manufacturing a drug. If any company uses that, breaks the patent law, manufactures the same drug and without permission of that company uses that brand name, that, according to our law, is considered as a spurious drug. It need not be fake drug. It need not be a drug which will affect the health of the

person who takes it. But, according to the law, it is a spurious drug that should actually come under the trade marks law. Why should it come under the patent law? So, whether the criminalisation of an act which actually belongs to elsewhere should be a practice here is the question that I have. My own feeling is that where the health of the consumers is directly involved and where the pharmaceutical companies which are adulterating drugs and which are producing fake drugs are involved, certainly the most stringent punishment should be meted out to them.

The other aspect is that the broader definition of spurious drugs should also be looked into under other various laws, whether there is violation of patent laws, whether there is violation of trade mark laws, etc. That is the second point.

Thirdly, what is the role of the Drug Inspectors of other countries, which are importing our drugs? The reason for asking this is, very recently, the hon. Members would also recall, drugs of Ranbaxy, a well-known pharmaceutical company in India, were banned in the USA. It was said that these were adulterated drugs or these drugs did not conform to the standards of the United States Federal Drugs Agency. When we went into the details of this, it was found that these drugs, which were being sent to the United States and which were banned there, were actually produced in two most sophisticated plants run by this company. Now if the drugs produced in the most sophisticated plants do not meet Good Manufacturing Practices and are banned in the United States, what will be the fate of Indian patients who are using those drugs?

The other aspect is, why did the American Inspectors have to come here and inspect the Indian factories? It was reported that when the US Inspectors came to India, they went and inspected these factories. They found that the factories were not producing drugs according to the GMP. They went back and gave the report. Then these drugs were banned. Sir, so far as the GMP is concerned, the Health Minister is so particular about it that he has closed down three vaccine manufacturing units in the country on the grounds that they are not conforming to...

DR. ANBUMANI RAMDOSS: We have not closed them. We have stopped manufacturing.

SHRIMATI BRINDA KARAT: Let me finish. Whether you have stopped it or closed it, that is a technical issue. Whatever it is. You have stopped them. You are not allowing them to manufacture it. Now you are not giving them funds to even upgrade those vaccine units. Why? According to you, it is not conforming to the GMP. As a result, what is happening? Sir, it is not a question of adulteration. Those vaccines are not adulterated. Those vaccines are not spurious. There are no complaints against those vaccines. Yet, because of the so-called GMP, you have stopped the production of these vaccines and you have allowed a very severe shortage to develop in many States of the country where the Universal Immunisation Programme has gravely

affected. Sir, we have written several letters to the hon. Minister in which we have given details of how many lakhs of doses are required and we have also written about the grave shortage. Sir, in his own State of Tamil Nadu, there is a shortage of vaccines. In Andhra Pradesh, there is a shortage of vaccines. Who is giving those vaccines? Private companies are giving those vaccines. What is happening to those private companies? Sir, children who have had those vaccines — again don't blame me and say that you are creating panic — the reality is, a number of those children have died. So the issue here is of Good Manufacturing Practices, fake drugs and safe drugs. There have to be similar standards for private sector vaccine manufacturing units. So far as the private sector in this country is concerned, I am sorry to say that there seems to be a special flexibility on behalf of the Health Ministry, which has permitted the American Inspectors to come here and say that these drugs were not up to their standards. Therefore, I believe it is India which gets affected. If an American company, if the American Government says that the Indian drugs are all spurious, then where is the question of spreading panic? You are doing it because you are not checking it.

Sir, I would also like to take this opportunity to say that in our country we have certain standards. Our public sector units are producing very important drugs. They are producing very important vaccines. They have very good track record. Please encourage them. Please do not starve them of funds. Let them manufacture what is required for our health system. That will be in the interest of Indian patients.

And the last point I want to make is this. Where is the machinery to implement this? Now having had a direct experience of the Drug Control Authority, what we have seen is that in the area of liberalisation, the basic regulation procedures required, whether it is for clinical trials, or, for new drugs being introduced in the market, are all gone. There is no regulatory mechanism today functioning in this country. And my point is this. No doubt, you are having severe penalty for fake drugs. At the same time, you are allowing clinical trials in this country, and allowing women and children and poor people of this country to be turned into guinea pigs for multinational companies because they are saving two-thirds, if not three-fourths, of expenses for having such clinical trials in India. So, this does not show a comprehensive approach towards the concerns of the Health Ministry, to the health concerns of our people, particularly, the poor in India. Therefore, machinery is required from the Drugs Control Authority, right here in Delhi, where there is a huge market for fake drugs. Everybody knows it. But how many inspectors of the Drug Control Authority are there. If you ask them, they will say, "We don't have anybody here who can actually do the job because there are no personnel." There are just two or three who are supposed to be checking all these things. According to the Drugs and Cosmetics rules, every year, there has to be an inspection of factory sites. Obviously, you do not have the personnel to do it. Therefore, to strengthen the Drug Control Authority, to bring regulatory mechanism in the pharmaceutical sector, to tame the private sector in its profit making motive

and to prevent exploitation of the vulnerability of ill people in this country, I believe, the Health Ministry does need, and does owe to this country, a more comprehensive approach to the health concerns of our people. Thank you, Sir.

श्री राजनीति प्रसाद (बिहार): उपसभापति महोदय, यह जो अमेण्डमेंट आया है, उस पर मैं ठाकुर जी के विचारों से सहमत हूँ। आपने इस अमेण्डमेट में life imprisonment दिया है, लेकिन इसमें जरूर maximum punishment, capital punishment होना चाहिए। अगर यह होता है तो जो खतरनाक दवा बनाते हैं, जिनकी दवा का standard नहीं है, जो मनुष्य के जीवन के लिए खतरनाक है, उसके लिए सबक रहेगा और डर भी रहेगा।

महोदय, मैं पेशे से एक वकील हूँ और मैंने 35 साल वकालत की है, लेकिन आज तक मैंने किसी व्यक्ति को इस एक्ट के तहत जेल में नहीं देखा है और मेरे हाथ से किसी व्यक्ति को acquittal हो गया हो या किसी को सजा हो गई हो, ऐसा मैंने नहीं देखा है। मैं बहुत दिनों तक कोर्ट में सरकारी वकील के पद पर भी रहा हूँ, लेकिन मैंने आज तक ऐसा नहीं देखा है। इसका मतलब क्या हुआ? मेरे ख्याल से इसका मतलब यह हुआ कि सरकार का ...**(व्यवधान)**... जो सरकार है, उसकी इस पर कोई जोर-जबर्दस्ती नहीं है, इस पर पूरा ध्यान नहीं है।

महोदय, पूरे शहर में कॉस्मेटिक और ड्रग्स की बढ़िया से बढ़िया दुकानें खुलती हैं, इतनी दवा की दुकानें खुलती हैं कि लगता है कि दवा की दुकानों की बाढ़ आ गई है, लेकिन जो खास दुकानें होती हैं, वही ज्यादा चलती हैं और बाकी जो दुकानें होती हैं, उनका चलने का प्रोवीजन उसमें होता ही नहीं है, क्योंकि ग्राहक लोग डरते हैं कि इस दुकान में खतरनाक दवा होगी, जाली दवा होगी। लोगों के अंदर यह विश्वास है कि जाली दवा भी बिकती है। यह जो जाली दवा बिकती है, इस पर हम लोगों को जरूर विचार करना चाहिए। इसके लिए एक नियम और कानून बनाना चाहिए। मैं स्वास्थ्य मंत्री जी से कहना चाहता हूँ कि देहात में डॉक्टर भी नहीं होता है, लोग दवा की दुकान पर जाते हैं और कहते हैं कि मेरे पेट में दर्द है, आप दवा दे दीजिए। तो वह दवा दे देता है और वह चला जाता है। सर, एक ऐसा भी कानून बनना चाहिए कि दवा की दुकान से बिना रसीद लिए कोई जाएगा नहीं। बिना रसीद की कोई दवा नहीं लेगा। ऐसा नहीं होने से, मान लीजिए हमने दवा ली, खाई और हम मर गए या कोई और मर गया, तो उससे कैसे आप छानबीन करेंगे कि कहां से दवा ली, किसने दवा दी? इसलिए यह भी कानून होना चाहिए, ऐसा कानून बनना चाहिए कि जो दवा बेचने वाला है, वह अगर दवा देता है, तो वह दवा रसीद के साथ देगा। सर, यह कमाल की जगह है हिंदुस्तान, जहां अभी भी, हमारे स्वास्थ्य मंत्री जी कह रहे हैं कि नहीं, आप गलत कह रहे हैं कि 30 परसेंट spurious drugs नहीं हैं। सर, यह हम लोग नहीं कह रहे हैं, बल्कि जो आपका आंकड़ा है, जो सर्वेक्षण रिपोर्ट है, वह कह रही है कि आपकी इतनी ड्रग्ज़ ऐसी हैं।

सर, ये जो ड्रग वाले हैं, ये हमारे यहां पोलिटिक्स में भी हैं। छोटी सी दवा की दुकान खोलते हैं, छोटी सी दवा की फैक्ट्री खोलते हैं और इतने करोड़ रुपए कमा लेते हैं कि हमारे यहां भी उनका बहुत ज़ोर हो जाता है। हमारे यहां पोलिटिक्स में भी ज़ोर हो जाता है। वे लाखों-करोड़ों रुपए कभी किसी को दे देते हैं, कभी किसी को दे देते हैं। अगर एक स्टैंडर्ड बना होगा, तो उसमें यह कमाई नहीं हो सकती है। जो spurious drugs हैं, उसी में कमाई होगी। इसलिए मेरी अपनी राय है, to cut short the matter कि इसमें death penalty जरूर होनी चाहिए और एक नियम यह भी बनना चाहिए कि जो भी दवा खरीदने जाए, बिना रसीद के किसी को दवा नहीं मिले। अगर बिना रसीद की दवा मिलेगी और वह खाएगा, तो फिर वह तो पता ही नहीं चलेगा कि वह दवा कहां से लाया? इसलिए उस पर कोई prosecution नहीं हो सकता है।

सर, एक अंतिम सवाल मेरा और है। हमारे स्वास्थ्य मंत्री जी यहां पर बैठे हैं। मैं यह जानना चाहूंगा कि आज तक इस तरह के The Drugs & Cosmetics Act में कितने लोगों को कितनी सज़ा मिली है?, इसकी जानकारी भी हम लोगों को चाहिए, धन्यवाद।

KUMAR DEEPAK DAS (Assam): Sir, I stand here to support this Bill which had been introduced on 22nd December, 2003 in Lok Sabha. The Bill had lapsed due to dissolution of the Lok Sabha. In this Bill, there are provisions for enhancement of the penalty, designation of courts for speedy trial of cases relating to spurious drugs and compounding of offences, etc. The present Bill brings forward new proposals for protecting the interests of the people. It is a fact that due to spurious drugs there are hundreds of cases which lead to serious problems and are even fatal. Sir, in the entire profession of physicians, spurious drugs has become a serious menace. We come across a number of cases where physicians and doctors face serious consequences for no fault of theirs because doctors prescribe a certain medicine, but the medicine purchased by the patient, turns out to be spurious. Thus, the consequences are being faced by the physicians. This is the main problem. It is the right time that the hon. Minister has brought this Bill to deal with such serious problems. What we have seen in our State of Assam is, the Government-supplied drugs are less effective. On the other hand, the drugs purchased from the market are more effective. Then, where is the fault lying? It should also be looked into because the Government suppliers are supplying spurious drugs to the Government hospitals. This is a serious problem in Assam. At the same time, the Drug Inspectors are sitting idle because they have no work to do. It is so because they are not acquainted with the problem and the distribution and manufacturing of spurious drugs is going on unabatedly. So, I would like to request the hon. Minister to look into all these problems. Sir, with these few words, I support the Bill.

SHRI BHARATKUMAR BHAVANISHANKAR RAUT (Maharashtra): Sir, I stand here to congratulate and thank the hon. Minister for bringing in such a Bill. But, at the same time, let me submit that I am not fully happy with what has been done. I can understand that a few steps have been taken, but are they enough to control the spreading of spurious and adulterated drugs in this country? That is to be seen.

Sir, I wish to say that bringing adulterated and spurious drugs into market should amount to murder because by consuming such drugs, if somebody dies, if somebody succumbs to them, then it is as bad as plotting a murder. It is a conspiracy of murder. So, I don't think the punishment which has been given here is enough to control the menace to this industry. I come from Maharashtra. This is one of the biggest States where medicines are produced. Many big companies are into it, but let me tell you — the hon. Minister must be aware of it — that the names of all the big companies and big brands appear in newspapers. Their bottles are

displayed in pharmaceutical stores and chemical stores. They actually do not produce; they do not manufacture those drugs. The drugs are manufactured outside. The manufactured drugs are outsourced. I can tell you — I am making a responsible statement here — that in my State, particularly the place from where I come, it is Mumbai and its surrounding areas, this type of manufacturing of drugs has become a semi-cottage industry. Many licensed and un-licensed, literate and illiterate, skilled and unskilled people get into drug manufacturing. They manufacture the drug and then it is packaged with a different big brand name. We have a place called '*dawa bazaar*'. In *dawa bazaar*, you come with me, I can give you any medicine in bulk. I can give you any medicine in kilograms, in quintals. Where is the quality control of those drugs? What is the mechanism we have to control it? Are you going to open every packet and check it? I think, we need to get into details of it; we need to go deeper into it. If your intention is right, I think, the implementation should also be on the same line, and it should be right. ***...(Interruptions)...*** Sir, I also wish to bring to your notice that there are many drugs for which there is heavy advertising in newspapers that they are tonics. Because of those attractive advertisements, I think, they take the people for a ride. In their advertisements they say that it is *shaktiwardhak*; it gives strength; by consuming it, the intelligence goes up. ***...(Interruptions)...*** The mothers give those types of drugs to their children during examination times because of advertisements. I have seen an advertisement where it says that if this medicine is taken, your child can remain awake the whole night and can study. You should have some control on this type of advertisements also because this amounts to taking people for a ride. We are befooling the people. Considering that we have literate and illiterate population which is likely to succumb to such advertisements, I think, the Minister would take cognizance of this.

I would like to bring to your notice another thing. As Brindaji has rightly said, where is the implementing authority and how do you monitor this? There has to be a very, very efficient mechanism that can control this. Otherwise, we are opening another den of corruption within the Government. In Maharashtra, we have the Food and Drug Administration, FDA. I tell you, FDA is a mine of corruption. It is a goldmine for corrupt people. People pay lakhs of rupees to get posted in FDA. Why do they do that? Because, in the name of inspection, the people from the FDA go to the manufacturing company, to the pharmaceutical company, and they extract money. If this type of situation happens, then the whole purpose of the amendment is defeated. I do not think this should happen in any case.

I would make another small point and it is slightly different than this, but I would like the Minister to take cognizance of this, and it is the prices. People do no go to a pharmacy and buy drugs to consume out of choice. It is an obligation. Because I am dying, my child is dying, my mother is dying, I go to the pharmacy and buy the medicine at a price that is printed. I think, the

Ministry should check what the manufacturing price of every drug is. If the manufacturing price of a drug is 'X', you can give 15 per cent or 20 per cent extra money. But, in the name of 'life-saving-drug', exorbitant prices have been quoted and people have to pay through their nose because they have to save somebody's life. As a Government, it is our duty and we should abide by this duty to ensure that we get drugs at a proper price. If the price is Rs.1,000, then you can take Rs.1,200 from me. But, if the manufacturing price, if the ingredients' cost is less than Rs.100, and still if you sell it for more than Rs.1,000, you sell it by creating panic saying, 'It is a life-saving-drug.' I think, we are misusing the law. I am sure, the Minister would take cognizance of this also and take steps to correct these.

I thank you for giving me the opportunity, though at the last minute.

DR. ANBUMANI RAMADOSS: Sir, firstly, I would like to thank the hon. Members for giving their very valuable comments. I, along with their concerns, would like to share my concerns as well as the Health Minister. I am not denying that there are no spurious drugs in the country, at all. Firstly, let me get to the definitions, because when you talk of spurious drugs, there are four concepts of drugs. One is the adulterated drug, second is the spurious drug, the third is misbranded drug, and the fourth is not-of-standard- quality. So, there are four categories of drugs, basically, and at this point of time I would not go into the definition. But, then, grossly I would like to say that an adulterated drug consists of wholly or partly any filthy or decomposed substance and all such issues. Spurious drug is manufactured under the name which belongs to another drug, imitation, label or mislabelling and all that. Then, there is 'misbranded'-- so coloured, quoted, or polished, or damaged, or concealed, or made to appear as therapeutic value than it is really of. The other quality of standard is 'of not of standard quality', which comes under the 'others', and the drugs comply with the standard set and it is in relation to cosmetics also, it complies with such standards. Sir, there have been a number of issues coming out in different newspapers, in the media about the quality and quantity of drugs. But before that I would like to say that the drug industry in India is today worth about Rs.60,000 crores. The export is worth Rs.20,000 to Rs.24,000 crores. The pharmaceutical industry is growing by about 10 to 15 per cent every year. India has the fourth largest in share volume and India supplies generics to different parts of the world, mostly the developing countries. India today also has the highest US FDA approved pharmaceuticals outside the United States, plus, it has got approximately about 600 to 650 units approved by the US FDA, by the Canadian FDA, by the European Union, by the Australian Union, which are some of the highest regulatory bodies in the world. It means that these people will not give permission to India if India has such a vast number of spurious drugs or adulterated drugs. The US FDA is the highest regulatory body in the world, United States Food and Drug Administration. When you say the India has got the highest US

FDA approved pharmaceuticals outside the United States, it definitely gives us a sense that there has been a lot of quality. I am not denying that there is no spurious drug at all. There is. We have done some studies ourselves, the industry has done some studies and now in the Government of India, I have asked the Health Ministry to put an end to these numbers, percentages and by about April, 2009 we will be getting the actual picture because currently there has been a huge massive survey being done by the Health Ministry, supported by the industry, to go intensively into the concept of spurious drugs and by what by earlier studies we have got, we have got numbers that about 3 to 3.5 per cent of the drugs in the country may be spurious, may be adulterated, misbranded or substandard, all categories, and not the content that as somehow my friends have been saying that 35 per cent of Indian drugs have been spurious and they attributed it to the WHO. The WHO stoutly denied it saying that they have not given any reports whatsoever about 35 per cent of Indian drugs being spurious. They have given it in newspapers and they have sent me also a communication saying that we have at no point of time said that 35 per cent of Indian drugs are spurious or not.

Sir, coming to this Bill, as I have already said, this had gone extensively and had been discussed in the Parliamentary Standing Committee and then by the Cabinet. In fact, twice I had to take it to the Cabinet. Then we have had some discussions and also we had to add on some factors. We have added on cosmetics into the Bill. Earlier cosmetic was not a part of this Bill. Secondly, we have added Ayurveda, Sidda, and Unani drugs also which will be regulated under this Bill. Earlier, it was not regulated under this Bill. Of course, the crux of this is the enhancement of the penalty. Sir, earlier the maximum penalty for spurious drugs causing death or grievous injury was about 5 to 7 years imprisonment and about Rs.10,000 fine. Sir, today the maximum punishment, if someone sells the spurious drugs which leads to death of grievous injury, the individual or the institution, the recommendation is minimum ten years and it can also be life imprisonment. So, today Judges are giving completely life imprisonment. Some of the judgements are coming. So, it is minimum ten years and which can go up to life imprisonment plus ten lakh rupees fine or three times the value of the confiscated goods, whichever is higher, plus the amount of ten lakh rupees or the three times the value of the goods whichever is higher should be compensated to the victims. If it is grievous, if there is a death, the relatives of the victims which have also been defined under the Bill and plus we have a stage of ten years, seven years, five years, three years. We are also compounding. It is according to the issue of adulterated or substandard. The substandard drugs, Sir, could be a case when a drug is properly manufactured but due to the transport mechanism, in transport there could be a breakdown, it can be substandard because of storage because there is no electricity, but the drug has been manufactured properly.

So, according to each category of substandard or adulterated or spurious or misbranded and all that, we have categorised the penalty and accordingly we want to go forward on that. The other thing which we have added on is that earlier the Police were mostly involved in filing cases. Since there were some issues about Inspector Raj and all other issues, now we have authorised the State Government to hand over this enforcement job to any Gazetted Officer, including the Police. So, they will have a wide spectrum of people visiting them, the drug inspectors and above category. Some of these issues are cognisable. So, we are framing a stern law so that nobody manufactures spurious drugs. Plus, Sir, we are recommending specially designated courts for trying out this. Sir, today, we all know that there have been a number of cases in various courts in India. When we initially recommended that there should be specific courts, but, at that time, Law Ministry said that it was not possible to have specific courts only for this. So, they have recommended and we have also accepted that there will specially designated courts in the existing courts to try these cases so that there will be more convictions and all that. Sir, enforcement today lies wholly with the State Governments. I am not shying away from the responsibility. We are now on the verge of formation of a Central Drug Authority. This was again a recommendation of Dr. Mashelkar. Not only Dr. Mashelkar, but this was a forty-year-old demand, the Bhuria Committee, the Haathi Committee, all of them recommended that India should have a Central Drug Authority on the lines of US FDA. I have introduced the Bill in the House and it has gone to the Standing Committee and, I think, today the Standing Committee was supposed to lay it on the floor of the House and we want to bring it out. Once that Central Drug Authority is formed, we will decentralise it from the Health Ministry, we will make it an autonomous institute, like TRAI. It will be a completely professional body, run by professionals. There will be technical persons, both from the industry, from the consumer, from the civil society. All will be part of their incorporation and it will be completely technical, scientific body to run the entire structure of regulation of the drug industry of India. We want to allay the apprehensions of the general public, including the Members here saying that the Government of India is very, very strongly against all these and we will go all out to do away with spurious drugs or adulterated drugs in the country and for that, Sir, in fact, hon. Shri Pranab Mukherjee, Minister of External Affairs had inaugurated a new building called 'FDA Bhawan' just a week ago, which is a beautiful Bhawan. Everything is ready. Some Members had pointed out that the Drug Control Authority is ill-equipped. One of the former Health Ministers, Mr. C. P. Thakur has also pointed out that. It was, but not any more. We have again shifted the building. We are increasing the manpower, and we are making a lot of things on-line. We have done numerous workshops in collaboration with the US FDA authorities. In fact, I had a meeting thrice with the US FDA Commissioner at my level, at my Secretary level, and in fact, my officers had

gone there. The WHO has been facilitating to strengthen our drug system with Canadian authorities and, in fact, the Canadian authorities are helping us out on technicalities, on global pattern, and we are also investing nearly about Rs. 200 crores on capacity building alone to improve, to modernise all the drug and food testing labs in the country, both in the Central Government labs, as well as, in the State Government labs plus all the manpower. We have had numerous workshops both in India and abroad. We have had faculties from abroad to incorporate the best clinical practices, the best pharmaceutical practices world wide so that we have the best quality in India. Plus, if we have any drug adverse reactions, we have initiated a concept called the Pharmaco-Vigilance Committee where it is going to be network of Committees all around the country for any drug reactions, whether due to a new drug or an old drug or any adverse reactions or anybody having any problem after consuming any drug, we will be noting them and they will be having strict surveillance, monitoring system out there. We are now enforcing them all over the country. Firstly, we have made it mandatory for all the medical colleges and all district headquarter hospitals to have all these things.

So, it is a wide network of things which we are trying to strengthen the capacity building and the manpower requirement. I agree with the hon. Members that we have manpower deficiency. When I say 'we', it is the State Governments which have deficiency. So, this will be addressed under the National Central Drug Authority. Today, the problem is, if Maharashtra does not give licence to a manufacturer, he will go to Goa and get a licence, manufacture drug and supply it back to Maharashtra. So, there are a lot of loopholes and lacunae in the administrative system itself. We don't know what the State Government is giving permissions for. We don't know. Some of the State Governments are giving permission for fixed dose combinations irrespective of our recommendation. We are trying to collect information from them. But, it is not forthcoming. At the same time, we cannot penalise them for not furnishing information. So, there are a lot of problems and issues which have to be sorted out. At the Central level, we give permission for new drugs, new vaccines, new blood products, etc. But then, for the existing drugs, we depend on State Governments and the authorities of the State concerned will give licence to them. So, under the Central Drug Authority, we are trying to streamline all these procedures. We are not taking away the power of the State Government. But, we are trying to coordinate with them. We are working with them in tandem and make it online so that any information will be both ways. The result would be, we will be knowing at which place, in which area things have happened and wish to address the problem. Also, we have asked them to fill up huge backlog of existing posts and new posts of Drug Inspectors. I have already said that Drug Inspectors already undergoing vigorous modern training.

I would like to reply to the questions raised by some of the hon. Members. One of my predecessors, former Health Minister has said that the Bill has been diluted because there is no

death penalty in it. Sir, my other predecessor, Smt. Sushma Swaraj, earlier had recommended death penalty for selling spurious drugs which leads to death or grievous injury. In fact, the Health Ministry also took note of that. But, then, it was the decision of the Cabinet. The Cabinet is of the opinion that since there has been a stringent mechanism involved with a minimum punishment of ten years and maximum of life imprisonment with fines and all that, there is no need for death penalty. The existing provisions will take care of that. So, the Government feels that at this point of time it is not necessary to have death penalty as such for anybody. But, at the same time, we are taking note of all these things. This is, no doubt, urgent. I, along with other hon. Members, feel that it is a fit case. But, there are other issues to be addressed at this point of time.

श्री रुद्रनारायण पाणि (उड़ीसा) : कानून को मानते नहीं हैं। स्मोकिंग के खिलाफ़...(व्यवधान)...

DR. ANBUMANI RAMADOSS: Mr. Pani, let me finish.

The enforcement mechanism, as I have already said, has been strengthened. The physical infrastructure, personnel, technicality, etc., have been strengthened and it is only a matter of time that once the Bill becomes an Act, things will move. There are two amendments. The first one is with regard to penal provisions and the second one is with regard to setting up of the Central Drug Authority. Once it comes into being, the entire mechanism is complete. He said about the US's FDA. Yes, we have been working on the US's FDA pattern, the Canadian pattern and the WHO is coordinating. They have come here. Our vision is, any drug manufactured in India should automatically be approved by the other global regulatory authorities. That sort of quality, that sort of standards is the vision of the Ministry of Health. And for that, we will go all out. We will go any extent so that that quality is imbibed into our system.

Shri Shantaram Naik talked about the CGHS. I would like to say that we are very strictly monitoring it. Whether it is the CGHS or non-CGHS, we are monitoring the entire mechanism. I don't think you have had any complaints in the last four years on the CGHS. Please don't be scared or apprehensive about the administration of the CGHS, because the drugs supplied to the CGHS are of the highest quality available in India. So, I feel that there should not be any apprehension about the drugs being supplied to the CGHS.

. I have replied to the point with regard to special designated courts. It is not only police, but any Gazetted Officer under the State Government can be enforcer.

I have already said that it is wrong to say that 35 per cent of drugs in India are spurious.

Shrimati Brinda Karat had brought about some of the issues. She said that only small pharmaceuticals were being focussed, and not the big pharmaceuticals. Whether it is small or big, all are equal to us, both in the States as well as in the Centre. And, if anybody is doing wrong or illegal things, definitely we will go against them.

Then, she raised the issue of Ranbaxy. The Ranbaxy is India's one of the best manufacturing units. It had nearly about 52 drugs approved by the USFDA. When a drug is approved by the USFDA that has one of the highest quality in the world. Suddenly, the USFDA authorities had given notices to them saying that they were not fulfilling the standards of the USFDA. In fact, they had not sent any notice to us; they had sent notices to the company only. And, till date we have not got any issue on that officially. Nevertheless, we enquired and found out that it was not an issue about the quality *per se*. It was an issue about documentation and procedure, which has been sorted out. It is between the Ranbaxy and the USFDA to sort it out. The USFDA inspectors go around the world and give approvals according to the situation.

Hon. Member also mentioned about three vaccine-manufacturing units. She said that the Health Ministry was favouring only the private sector, and not the public sector. Sir, I would like to submit that this issue has been going around for some time. We have three vaccine-manufacturing units — one is the PII, Cunoor; second is the CRA, Kasauli; and the third is the BCG, Guindy. These are all public sector units, supplying vaccines to the Ministry of Health. Late last year, we had to take a decision to ask these units to stop manufacturing vaccines because they did not conform to the Indian Good Manufacturing Practice (GNP). In India, there are three qualities. First quality is the Indian GMP, which is called the Schedule 'M'. That is the basic quality. No institution, whether it is a pharmaceutical or vaccine-manufacturing unit, without having even an Indian GMP can't manufacture anything. The second quality is the WHO GMP, and third is the WHO prequalification. The WHO pre-qualification is, again, one of the highest in the world. And, these three units did not conform to the standards. They did not have even basic Indian GMP. ...*(Interruptions)*... I am coming to your point. I sent my Drug Controller General and some officers to her. For one-and-half hours, they explained her very clearly what had happened. I don't know why she wants to raise it again. ...*(Interruptions)*... I will answer all your questions. ...*(Interruptions)*...

SHRI VIJAY JAWAHARLAL DARDA: Did you send Baba Ramdev?

DR. ANBUMANI RAMADOSS: No; no, he is not my officer. ...*(Interruptions)*... Before that, Sir, I would come to another issue about the WHO. Every 3-4 years, they go around the world and, then, they recognize the National Regulatory Authority (NRA).The NRA, in India, is the Drug Controller General of India. They call it the NRA. Why they recognise it because the NRA in that country gives the WHO GMP and the WHO pre-qualification on behalf of the World Health Organization. That's why they go to all the countries and see whether the NRA is working properly or not. So, they are the givers of the WHO GMP. They had been coming to India much earlier as well. They had gone to Vietnam also. They derecognised the Vietnam's NRA. When they came to India they found out that these public sector units, which were manufacturing vaccines, did not have even the basic Indian GMP.

SHRIMATI BRINDA KARAT: They found that!

DR. ANBUMANI RAMADOSS: Yes, they found that. They went around the country and visited all the public and private sector units.

PROF. P.J. KURIEN (Kerala): You did not know that!

DR. ANBUMANI RAMADOSS: We knew that but, then, since the vaccine manufacturing capacity had to be there*...(Interruptions)...* In fact, we spent nearly about Rs. 50 crores for all these three units at some point of time to make them Indian GMP. After spending all this money repeatedly and regularly, they still did not conform to that.

SHRIMATI BRINDA KARAT: Sir, I am sorry*...(Interruptions)...*

DR. ANBUMANI RAMADOSS: No; let me finish. But, I would like her to put a separate question for this. This discussion is regarding the Bill. For vaccine manufacturing unit and why we had to stop that, I think, she could put it as a separate question and I would be happy to answer that. I just want to touch.. *...(Interruptions)...*

SHRI RUDRA NARAYAN PANY: Sir, we agree with you. But, most of her Party Members smoke. *...(Interruptions)...* उनकी पार्टी के ज्यादातर मैम्बर्स स्मोकिंग करते हैं। ...(**व्यवधान**)...

MR. DEPUTY CHAIRMAN: It has nothing to do with smoking. *...(Interruptions)...*

DR. ANBUMANI RAMADOSS: She is not angry with me, Sir. *...(Interruptions)...* She is not angry with me. *...(Interruptions)...* We had to take a decision to ask these manufacturing units to stop manufacturing these vaccines till such time they conform to Indian GMP. So, we are not going to close them down. We are not going to put anybody out of work. We are giving them the salaries. I have asked my Drug Controller General to go around these units and give me a realistic recommendation and appoint an expert team to see what could be done on this. Sir, out of these three units, two units were started a hundred years back by the Britishers. They were started in hill stations. Today, there is a logistic problem out there about expansion. We have spent a lot of money on them to be upgraded and modernised, but, still they do not conform to the Indian GMP. So, again we have a problem. Subsequently, Sir, we are also going to start a state-of-art technology, cutting edge technology, a new vaccine manufacturing unit, to supply to the entire country. It is going to be a hundred per cent public unit; a Government of India unit. And, none of the employees in these institutions is going to be retrenched or sent out of work. They will be given an option to come there plus we are not going to close down that. The Drug Controller General has already given a recommendation that these units will be again made functional after conforming to the Indian GMP and after fulfilling all these logistics. All these technical things are there in it. It is not that we are just going to shut all these things.

My colleague has said that there has been acute shortage of vaccines and all that. All these issues have been sorted out. In fact, a delegation had come. About 20 MLAs

from West Bengal had come along with their Health Minister. We have sorted out the problem not only in respect of West Bengal, but for the entire country. There were not gross shortages, as the hon. Member has said. There were some shortages of one or two things, which have already been sorted out. And I don't see there is a problem anywhere in the country currently due to that. It is not that we were not buying vaccines from the private manufacturers earlier. Approximately, every year, we purchase vaccines worth about Rs. 750 crores. Out of this, Rs. 40-50 crores worth of vaccines, the public manufacturing units were giving us. That is, Rs. 700 crores worth of vaccines the private manufacturers were giving us. The public units have this capacity. We need to move on. Vaccines need a cutting edge technology. The babies are given vaccines, so, the quality has to be there. If these institutions do not have any quality, we cannot just passively sit and, and say, 'okay, you manufacture this.' It is not that just for a few employees, we want to do this. No party is saying that they are in-charge of all employees of the country. Every party has got the right to plead for employees' safety. I don't want to go into the intricacies of all that. I will move on.

Sir, there was a point raised about similar standards for public and private institutions. Definitely, it has to be there. She said that children died because of vaccine provided by one private manufacturer. It is not attributed to them. The final report has not yet come, but, the initial reports say that it is not attributed to the quality of the vaccine. It is attributed to the giving of vaccine. The A.N.M there, she did not give it properly. The same thing happened in Tamil Nadu. In Tamil Nadu it was purchased from the public sector; from a Government manufacturing unit. And, that, again, was attributed, not to the quality of the vaccine, but to the improper way of handling the injections and all that. It is not easy to say that the Government is doing or not doing this. When you go to the intricacies, you have to understand what situation we are going through.

A point was raised about clinical trials in MNCs. Definitely, at no point of time, the Government will allow multinational drug companies or Indian drug companies to use Indians as guinea pigs for any testing. At the same time, when you say that pharmaceutical industry is growing in India, we need to move forward keeping very strict sense the life and safety of all the patients and the general public as well. Today, Sir, the MNCs are not allowed to have a clinical phase trial-I in the country. They are permitted to do only phase trial-II alongwith the multi-centric trial. Sir, at the same time, these trials have to go out to other parts of the world as well. I would again like to say that, I would like to answer her if she puts a separate question on clinical trials. I will be more than happy to answer that, allaying all the apprehensions within the House and outside the House. Also, I am personally going to review all the clinical trials happening in the country and would try to restructure it. If there is any issue, I would like the Members and non-Members outside the House to give me information then and there.

Mr. Prasad, mentioned about convictions. A number of convictions are there which I will, definitely, compile and I will give you the number of convictions under the Drugs and Cosmetic Act.

As for the issues raised by the Member from Assam on the quality of the Act, maybe, I will take up those issues with the State Government of Assam. As for Dawa Bazaar, I will, definitely, ask my Drug Controller to take cognisance of this issue. As far as prices of drugs are concerned, my colleague Shri Ram Vilas Paswan is doing a lot on price control. We are all, as a Government, pro-aam aadmi, trying to make it that at no point of time these drugs go out of reach. India has the lowest cost of drugs in the entire world and we want to keep that way. Plus, there are nearly about 200 - 300 drugs for which price mechanism has been there. These are mostly used drugs. So, all steps will be taken.

Again, advertisement is one good issue which you have raised. I have also taken up this issue with my officials. This comes under the Drugs and Magic Remedies Act. So, anybody issuing a frivolous advertisement, or, misleading advertisement and all that, he will be branded under that Act. We are trying to amend the Drugs and Magic Remedies Act because some of them are coming not only for drugs but also for cosmetics. All these things are being considered and we will be taking up all these issues. With these words, Sir, I, once again, kindly request you and all the Members to support this.

MR. DEPUTY CHAIRMAN: The question is:

"That the Bill further to amend the Drugs and Cosmetics Act, 1940, be taken into consideration."

The motion was adopted.

MR. DEPUTY CHAIRMAN: We shall now take up clause-by-caluse consideration of the Bill. In clause -2, there are seven amendment nos. 4-10 by Dr. Anbumani Ramadoss.

AMENDMENT OF SECTION 27

DR. ANBUMANI RAMADOSS: Sir, I move:

8. That at page 2, *for* lines 1 to 3, the following be *substituted*, namely, -

"2. In section 27 of the Principal Act,

(i) in clause (a),-

(A) for the figure, alphabet and the words "17B or which" the figure, alphabet and the words "17B and which".

9. That at page 2, line 4, *for* the bracket and alphabet "(A)", the bracket and alphabet "(B)" be *substituted*.

10. That at page 2, line 11, *for* the bracket and alphabet "(B)", the bracket and alphabet "(C)" be *substituted*.

11. That at page 2, *after* line 26, the following be *inserted*, namely-

"(iii) parent of the minor victim; or"

12. That at page 2, line 27, *for* the bracket and roman numeral "(iii)", the bracket and roman numeral "(iv)" be *substituted*.

13. That at page 2, line 30, *for* the bracket and roman numeral "(iv)", the bracket and roman numeral "(v)" be *substituted*.

14. That at page 2, line 45, *for* the words "fine which shall not be less than one lakh rupees", the words "fine which shall not be less than one lakh rupees or three times the value of the drugs confiscated, whichever is more" be *substituted*.

The questions were put and the motions were adopted.

Clause 2, as amended, was added to the Bill.

MR. DEPUTY CHAIRMAN: Now, I shall take up insertion of a new clause, clause - 2A. There is one amendment for insertion of a new Clause -2A, No. 11, by Dr. Anbumani Ramadoss.

AMENDMENT OF SECTION 27

DR. ANBUMANI RAMADOSS: Sir, I move:

15. That at page 3, *after* line 11, the following be *inserted*, namely,-

"2A. In section 27 A of the principal Act, for clauses (i) and (ii), the following clauses shall be substituted, namely -

(i) any cosmetic deemed to be spurious under section 17 D or adulterated under section 17E shall be punishable with imprisonment for a term which may extend to three years and with fine which shall not be less than fifty thousand rupees or three times the value of the cosmetics confiscated, whichever is more;

(ii) any cosmetic other than a cosmetic referred to in clause (i) in contravention of any provisions of this Chapter or any rule made thereunder shall be punishable with imprisonment for a term which may extend to one year or with fine which may extend to twenty thousand rupees, or with both."

The question was put and the motion was adopted.

Clause-2A was added to the Bill.

Clauses 3 and 4 were added to the Bill.

MR. DEPUTY CHAIRMAN: I shall now take up insertion of new clause 4 (a). There is one amendment for insertion of new clause (4), No. 12, by Dr. Anbumani Ramadoss.

NEW CLAUSE - 4A

DR. ANBUMANI RAMADOSS: Sir, I move:

16. That at page 3, *after* line 17, the following be *inserted*, namely-

"4A. In section 29 of the principal Act, for the words, "five hundred rupees", the words "five thousand rupees" shall be substituted."

Clause-4A was added to the Bill.

MR. DEPUTY CHAIRMAN: Now, we shall take up Clause 5 of the Bill. There are two amendments (Nos. 13 and 14) by the hon. Minister.

CLAUSE 5 - Amendment of Section 30

DR. ANBUMANI RAMADOSS: Sir, I move:

13. That at page 3, *for* line 34, the following be *substituted*, namely-

'(iii) in clause (c), for the words "five thousand rupees" the words "fifty thousand rupees" shall be substituted.

14. That at page 3, *for* line 35, the following be *substituted*, namely-

'(b) in sub section (2), for the words "ten years, or with fine, or with both" the words "two years, or with fine which shall not be less than ten thousand rupees or with both" shall be substituted.

The questions were put and the motions were adopted.

Clause 5, as amended, was added to the Bill.

MR. DEPUTY CHAIRMAN: Now, we shall take up clause 6. In clause 6, there are four amendments (Nos. 15 to 18) by the hon. Minister.

CLAUSE 6 - Amendment of Section 32

DR. ANBUMANI RAMADOSS: Sir, I move :

15. That at page 3, lines 40 to 43, be *deleted*.

16. That at page 3, line 44, *for* the bracket, alphabet and words "(c) any officer" the bracket, alphabet and words "(b) any gazetted officer" be *substituted*.

17. That at page 4, line 1, *for* the bracket and alphabet "(d)", the bracket and alphabet "(c)" be *substituted*.

18. That at page 4, line 2, *for* the bracket and alphabet "(e)", the bracket and alphabet "(d)" be *substituted*.

The questions were put and the motions were adopted.

Clause 6, as amended, was added to the Bill.

MR. DEPUTY CHAIRMAN: Now, we shall take up Clause 7. There are two amendments (Nos. 19 and 20) by the hon. Minister.

CLAUSE 7 - Insertion of new section 32 B. Compounding of certain offences

DR. ANBUMANI RAMADOSS: Sir, I move :

19. That at page 4, *for* lines 8 to 10, the following be *substituted*, namely, -

"32B. (1) Notwithstanding anything contained in the Code of Criminal Procedure, 1973, any offence punishable under clause (b) of sub-section (1) of section 13, section 28 and section 28A of this Act whether".

20. That at page 4, *after* line 18, the following proviso be *inserted*, namely, -

"Provided further that in cases of subsequent offences, the same shall not be compoundable".

The questions were put and the motions were adopted.
Clause 7, as amended, was added to the Bill.

MR. DEPUTY CHAIRMAN: Now, we shall take up clause 8. In clause 8, there is one amendment (No. 21) by the hon. Minister.

CLAUSE 8 - Amendment of Section 33

DR. ANBUMANI RAMADOSS: Sir, I move :

21. That at page 4, *for* lines 27 and 28, the following be *substituted*, namely, -

'8. In section 33 of the principal Act, in sub-section (2),-

(i) after clause (dd), the following clause shall be inserted, namely,-

"(dda) prescribe under clause (d) of section 17E the colour or colours which a cosmetic may bear or contain for the purposes of colouring;";

(ii) in clause (p), the word "and" occurring at the end shall be deleted;

(iii) in clause (q), the word "and" shall be inserted at the end;

(iv) after clause (q), the following clause shall be inserted, namely,-

The question was put and the motion was adopted.
Clause 8, as amended, was added to the Bill.

MR. DEPUTY CHAIRMAN: After this, there is insertion of new clauses 8A to 8D. There is one amendment (No. 22) for insertion of New Clauses 8A to 8D by the hon. Minister.

New Clauses 8A to 8 D.

DR. ANBUMANI RAMADOSS: Sir, I move :

22. That at page 4, *after* line 30, the following be *inserted*, namely, - Amendment of section 33-I.

'8A. In section 33-I of the principal Act,-

(a) in sub-section (1),-

(i) for clause (a), the following clause shall be substituted, namely:-

"(a) any Ayurvedic, Siddha or Unani drug-

(i) deemed to be misbranded under section 33E,

(ii) deemed to be adulterated under section 33EE, or

(iii) without a valid licence or in violation of any of the conditions thereof, as required under section 33EEC, or

shall be punishable with imprisonment for a term which may extend to one year and with fine which shall not be less than twenty thousand rupees or three times the value of the drugs confiscated, whichever is more;";

(ii) in clause (b), for the words "five thousand rupees", occurring at both the places, the words "fifty thousand rupees or three times the value of the drugs confiscated, whichever is more" shall be substituted;

(iii) after clause (b), the following clause shall be inserted, namely;-

"(c) any Ayurvedic, Siddha or Unani drug in contravention of the provisions of any notification issued under section 33EED shall be punishable with imprisonment for a term which may extend to three years and with fine which may extend to fifty thousand rupees or three times the value of the drugs confiscated, whichever is more.";

(b) in sub-section (2), for the words "three months and with fine which shall not be less than five hundred rupees", the words "six months and with fine which shall not be less than ten thousand rupees" shall be substituted.

Amendment of section 33-J.

8B. In section 33J of the principal Act,-

(a) in clause (a), for the words "two thousand rupees", the words "fifty thousand rupees or three times the value of the drugs confiscated, whichever is more" shall be substituted;

(b)in clause (b), for the words "five thousand rupees" occurring at both the places, the words "one lakh rupees or three times the value of the drugs confiscated, whichever is more" shall be substituted;

(c) in clause (c), for the words "six months and with fine which shall not be less than one thousand rupees", the words "one year and with fine which shall not be less than twenty thousand rupees or three times the value of the drugs confiscated, whichever is more" shall be substituted.

8C. After section 33K of the principal Act, the following sections shall be inserted, namely,- — Insertion of new sections 33KA and 33KB

"33KA. Every person, not being the manufacturer of any Ayurvedic, Siddha or Unani drug or his agent for the distribution thereof, shall, if so required, disclose to the Inspector the name, address and other particulars of the person from whom he acquired the Ayurvedic, Siddha or Unani drug. — Disclosure of name of manufacturer, etc.

33KB. Every person holding a licence under clause (c) of section 33EEC shall keep and maintain such records, registers and other documents as may be prescribed and shall furnish to any officer or authority exercising any power or discharging any function under this Act such information as is required by such officer or authority for carrying out the purposes of this Act.". — Maintenance of records and furnishing of information.

8D. In section 33N of the principal Act, in subsection (2),- — Amendment of Section 33N.

(i) in clause (gga), the word "and" occurring at the end shall be deleted;

(ii) after clause (gga), the following clause shall be inserted, namely,-

"(ggb) prescribe the records, registers or other documents to be kept and maintained under section 33KB; and".

The question was put and the motion was adopted.

The New Clauses 8A to 8D were added to the Bill.

Clauses 9 to 10 were added to the Bill.

MR. DEPUTY CHAIRMAN: Now, we shall take up Clause 1. In clause 1, there is one amendment (No. 2) by the hon. Minister.

CLAUSE 1 - Short title and commencement.

DR. ANBUMANI RAMADOSS: Sir, I move :

2. That at page 1, line 2, *for* the figure "2005", the figure "2008" be *substituted.*

The question was put and the motion was adopted.

Clause 1, as amended, was added to the Bill.

MR. DEPUTY CHAIRMAN: After this, there is insertion of new Clauses 1A to 1D. There is one amendment (No. 3) for insertion of new Clauses 1A to 1D by the hon. Minister.

NEW CLAUSES -1A to 1D

DR. ANBUMANI RAMADOSS: Sir, I move :

3. That at page 1, *after* line 7, the following be *inserted*, namely, -

"1A. After section 17D of the Drugs and Cosmetics Act, 1940 (hereinafter referred to as the principal Act), the following section shall be inserted, namely,- — Insertion of new section 17E.

23 of 1940.

"17E. For the purposes of this Chapter, a cosmetic shall be deemed to be adulterated,- — Adulterated cosmetics.

(a) if it consists in whole or in part, of any filthy, putrid or decomposed substance; or

(b) if it has been prepared, packed or stored under insanitary conditions whereby it may have been contaminated with filth or whereby it may have been rendered injurious to health; or

(c) if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or

(d) if it bears or contains, for purposes of colouring only, a colour other than one which is prescribed; or

(e) if it contains any harmful or toxic substance which may render it injurious to health; or

(f) if any substance has been mixed therewith so as to reduce its quality or strength"

"1B. In section 18 of the principal Act, in clause (a), for sub-clause (ii), the following sub-clause shall be substituted, namely,- — Amendment of section 18

(ii) any cosmetic which is not of a standard quality, or is misbranded, adulterated or spurious;".

"1C. In section 26A of the principal Act, for the word "prohibit", the words "regulate, restrict or prohibit" shall be substituted. — Amendment of Section 26A.

"1D. After section 26A of the principal Act, the following section shall be inserted, namely,- — Amendment of new section 26B.

"26B. Without prejudice to any other provision contained in this Chapter, if the Central Government is satisfied that a drug is essential to meet the requirements of an emergency arising due to epidemic or natural calamities and that in the public interest, — Power of Central Government to regulate or restrict.

it is necessary or expedient so to do, then, that Government may by notification in the Official Gazette, regulate or restrict the manufacture, sale or distribution of such drug".		manufacture, etc. of drug in Public interest.

The questions were put and the motions were adopted

The New Clauses 1A to 1D were added to the Bill.

MR. DEPUTY CHAIRMAN: Now, we shall take up the Enacting Formula. In the Enacting formula, there is one amendment (No. 1) by the hon. Minister.

Enacting Formula

DR. ANBUMANI RAMADOSS: Sir, I move :

1. That at page 1, line 1, *for* the word "Fifty-sixth", the word "Fifty-ninth" be *substituted*.

The question was put and the motion was adopted.

The Enacting Formula, as amended, was added to the Bill.

The Title was added to the Bill.

DR. ANBUMANI RAMADOSS: Sir, I move :

That the Bill, as amended, be passed.

The question was put and the motion was adopted.

MR. DEPUTY CHAIRMAN: Now, there is a statement by Shri Pranab Mukherjee. *...(Interruptions)...*

SHRI PRASANTA CHATTERJEE (West Bengal): Sir, the Prime Minister assured the House on *...(Interruptions)...*

THE MINISTER OF EXTERNAL AFFAIRS (SHRI PRANAB MUKHERJEE): Sir, the statement is meant for the information of the hon. Members. If the Members are not interested in listening to the Statement, with your permission, I would like to lay it on the Table of the House. *...(Interruptions)...*

MR. DEPUTY CHAIRMAN: Okay. *...(Interruptions)...*

STATEMENT BY MINISTER

India's Civil Nuclear Energy initiative

THE MINISTER OF EXTERNAL AFFAIRS (SHRI PRANAB MUKHERJEE): Sir, I make the following Statement on India's Civil Nuclear Energy Initiative. *...(Interruptions)...*